MAY - 4 2001 K003626

16. 510(k) Summary

Submitter's Name: Sunrise Medical HHG Inc.
Respiratory Products Division
100 DeVilbiss Drive
Somerset, PA 15501
Allan R. Jones
814-443-7618

Date Prepared: November 20, 2000

Device Name: Humidifier, Respiratory Gas, (Direct Patient Interface)

FDA Product Code: BTT

Common or Usual Name: Humidifier

DeVilbiss Model Number: 9100D

Trade Proprietary Name: DeVilbiss Model 9100D Humidifier

Established Registration Number: DeVilbiss # 2515872

FDA Classification: Class II Device

Equivalent Legally Marketed Predicate Device:

Legally Marketed Predicate Devices	**510(k) Registration #**
Respironics Oasis Humidifier	K964653

Description of Device:

The basic humidifier assembly consists of a chamber formed by two halves, a chamber base and a chamber lid, which are molded from a polycarbonate resin. The assembly also includes an elastic o-ring for sealing the chamber halves, slide latches to hold the chamber halves together during operation, and a 15" long X 22mm inside diameter connection tube.

The humidifier chamber is designed to hold enough water for a minimum of 12 hours of operation at the maximum humidity output. The chamber is constructed from two halves that can be easily disassembled for cleaning. With the use of a sealing o-ring and six slide latches, the maximum operating pressure of the humidifier is 40.0 cmH2O.

The configuration of the chamber is such that the inlet and exhaust connections, which are located on the chamber lid, are interchangeable to reduce setup complications. The 15" long 22mm-diameter connection tube is to be kink resistant and long enough to connect any CPAP device currently on the market to a port on the humidifier when placed beside or on top of the humidifier chamber. The humidifier chamber base incorporates four non-latex polyurethane polymer elastic feet for unit stability.

The humidifier chamber, excluding the sealing o-ring, is considered dishwasher safe if placed on the top rack of the dishwasher.

Statement of Intended Use:

The 9100D DeVilbiss Humidifier is to be used in conjunction with most positive airway pressure devices that require humidity to be added to the circuitry. The majority of its use will be with Continuous Positive Airway Pressure and Bilevel Positive Pressure devices used in the treatment of Obstructive Sleep Apnea. The humidifier may also be used with noninvasive positive pressure ventilation devices used in the market for that purpose. The 9100D humidifier can be used with any legally marketed CPAP, Bilevel, or noninvasive ventilation device on the market.

The DeVilbiss Humidifier is not intended to be used with auto-adjusting CPAP devices that use snoring, as detected through the patient air circuitry, for the adjustment of the therapy pressure. The humidifier is known to attenuate the snoring frequency signal as it passes through the humidifier and patient circuitry, which prevents the auto-adjusting CPAP device from detecting most snoring.

The DeVilbiss humidifier is for use in the home environment and is to be used only on the order of a physician. The humidifier can be used with CPAP and Bilevel devices which have a maximum operating pressure of 20 cm H_20. The humidifier can also be used with noninvasive ventilation devices that have a maximum operating pressure of 40 cmH_20. Performance of non-DeVilbiss CPAP systems used with the DeVilbiss humidifier should be tested to confirm proper operation before use.

Technological Characteristics:

The DeVilbiss Model 9100D Humidifier is equivalent in functional characteristics to the existing legally marketed predicate device. Humidification performance output testing and humidifier system pressure loss testing were performed on the new DeVilbiss Model 9100D Humidifier and the predicate device. The test results show that the DeVilbiss Humidifier is substantially equivalent to the existing legally marketed predicate device and that both devices will produce similar humidification treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2001

Mr. Allan Jones
Sunrise Medical HHG Inc.
Respiratory Product Division
100 DeVilbiss Drive
Somerset, PA 15501-0635

Re: K003626
DeVilbiss Humidifier
Regulatory Class: II (two)
Product Code: BTT
Dated: March 19, 2001
Received: March 20, 2001

Dear Mr. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

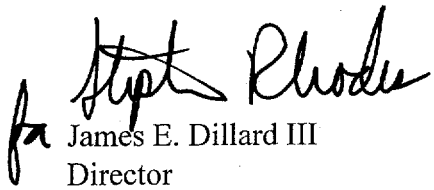
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003626

510(k) Number: (if known): ~~Not yet assigned~~

Device Name: DeVilbiss Model 9100D Humidifier

Indications For Use:

The 9100D DeVilbiss Humidifier is to be used in conjunction with any positive airway pressure device that requires humidity to be added to the circuitry. The majority of its use will be with Continuous Positive Airway Pressure and Bilevel Positive Pressure devices used in the treatment of Obstructive Sleep Apnea. The humidifier may also be used with noninvasive positive pressure ventilation devices used in the market for that purpose. The 9100D humidifier can be used with any legally marketed CPAP, Bilevel , or noninvasive ventilation device on the market.

Division of Cardiovascular & Respiratory Devices
510(k) Number K003626